Request for OMB Review

Title: Assessing the knowledge, attitudes, and behaviors of the public regarding appropriate antibiotic use for upper respiratory infections

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A. Justification

A.1. Circumstances Making the Collection of Information Necessary

On January 9, 2009, CDC received OMB approval for the generic concept of health marketing (Health Marketing, 0920-0798) to provide feedback on the development, implementation and satisfaction regarding public health services, products, communication campaigns, and information.

Under Health Marketing, OMB has agreed to expedite review of proposals for data collections for survey/information materials development and customer satisfaction surveys only. OMB will generally review such requests within ten business days.

The specific project that this clearance covers is the National Center for Immunization and Respiratory Diseases (NCIRD), Get Smart: Know When Antibiotics Work campaign's study entitled: Assessing the knowledge, attitudes, and behaviors of the public regarding appropriate antibiotic use for upper respiratory infections.

In 2003, the Centers for Disease Control and Prevention (CDC) launched a campaign, Get Smart: Know When Antibiotics Work, to reduce inappropriate antibiotic use and slow down rising rates of antimicrobial resistance. The Get Smart campaign has three objectives: 1) to promote clinician adherence to appropriate prescribing guidelines for URIs; 2) to decrease demand for antibiotics for viral URIs among healthy adults and parents of young children; and 3) to increase patient adherence to antibiotic regimens prescribed for URIs. The campaign is aimed at the general public and healthcare providers, because the knowledge, attitudes, and behaviors of both patients and providers contribute to antibiotic prescribing and antibiotic use. The primary focus of the Get Smart campaign is the development and dissemination of educational materials.

In November 2006, The Get Smart: Know When Antibiotics Work campaign conducted an external review of the campaign with a board of experts in the fields of medicine and academia. One of the recommendations from the board was that the campaign should develop messages to inform the public about the dangers of adverse drug events (ADEs) related to antibiotic use.

Substantial and consistent evidence for the importance of ADEs has been mounting. During 2004 and 2005, an estimated 700,000 U.S. patients were treated annually for adverse drug events; seven of the top fifteen drugs commonly implicated in ADEs treated in emergency departments were antibiotics (Budnitz, Pollock, Weidenbach, et al, 2006). In their ground-breaking, rigorous research on emergency visits for antibiotic-associated adverse events, Shehab et al (2008) estimated conservatively that 142,500 emergency department visits each year are for ADEs and noted that "the rate of ED visits for antibiotic-associated adverse events is one-half of the rate of ED visits attributable to 'high risk' medications" and about 3 times higher than that attributable to several classes of widely used medications, including aspirin. They concluded that "decreasing inappropriate antibiotic use by even a small percentage could

substantially reduce the number of patients who experience antibiotic-associated adverse events." In calculations based on the Shehab et al article and the weight of other research, Linder (2008) concluded that "For most acute respiratory tract infections, antimicrobial resistance is irrelevant. For an individual patient, the risks are greater than the benefits."

According to Gleckman and Borrego (1997), "The most important approach to decreasing antibiotic-related side effects is judicious use of these drugs." Educating the public and clinicians about appropriate use of antibiotics and possible adverse events is one method that could help reduce antibiotic resistance and adverse drug events.

Most recently, exploratory in-depth interviews with 9 primary care physicians by Balch Associates (2009) suggested that such physicians are already aware of current CDC/AAP guidelines and use a variety of ways to conform to them in a time-pressed health care practice in which patients and parents often request or demand antibiotics for upper respiratory infection systems. All interviewees reported usually NOT prescribing antibiotics unless they see strong evidence that the URI is bacterial rather than viral; this is the main reason they are reluctant to prescribe antibiotics. This is the reason —if any—that they present to curious or insistent patients, sometimes backed up with educational materials.

They explain to patients why antibiotics won't help, and reassure them that symptoms will improve on their own. In some cases, they also mention the risk of creating resistance for the community and the individual or specific common side effects that may affect patients who seem prone to them. However, they usually do NOT mention adverse drug events unless specifically asked; they consider it more likely to scare patients from taking antibiotics when needed than to help them make wise decisions. More of these physicians than not consider adverse events rare.

Consistent with previous qualitative research on primary care physicians by Barden, Dowell, Schwartz and Lackey (1999), physicians in the Balch Associates interviews (2009) have to handle frequent patient requests for antibiotics and have experienced time-consuming resistance to the physician's reluctance or denial to prescribe them. Like those in the Barden et al study, they also welcomed the idea of patient materials to make their efforts more efficient or less necessary. They offered several suggestions, including talking points for physicians and several kinds of materials for patients.

In view of these findings and the limited recent in-depth research on what patients think, feel, and experience with antibiotics and educational materials it is clear that formative in-depth qualitative study with adult patients and parents of young children is essential to explore their needs for information, to develop such materials, and to disseminate them strategically.

A.2. Purpose and Use of Information Collection

The overall goal of the study is to inform the National Center for Immunization and Respiratory Diseases (NCIRD) and subject matter experts (SMEs) of communication strategies most likely to encourage, enable, and facilitate proper use of antibiotics by prescribing physicians, patients, and parents. The

resulting information is intended to recommend effective communication strategies and types of materials that are personally relevant, comprehensible, credible, and motivating to the target audience(s).

Specific study objectives for all target audiences are to explore knowledge, attitudes, experiences, and behaviors of patients and parents of patients about:

- the appropriate use of antibiotics for upper respiratory infections;
- antibiotic resistance;
- adverse drug events related to antibiotics; and
- desired antibiotic-related information about incurrent and potential education efforts about antibiotic use (messages, communication tools, sources, openings, and message channels and vehicles)

This formative study will provide a foundation for the development of the new campaign materials, based on answers to the key questions for consumer-based health communication (Sutton, Balch, and Lefebvre 1995) and reactions in the focus groups to sample messages. The key questions are:

1. Target: Who is/are the target audience(s) and what are they like?
2. Action: What specific behavior(s) do we want them to take?
3. Benefit: What specific benefit best motivates them to take the desired action?
4. Support: What support best makes the promise of the benefit credible?
5. Openings and Message Vehicles: When, where, and under what circumstances is the target audience most open to receiving or acting on the message and what vehicles might best deliver it there?

A total of six (6) focus groups will be conducted; three (3) each with the following audience segments:

- Mothers of children ages 2-12 years old. Neither they nor their children have any morbidity that raises the need for antibiotics.
- Healthy adults ages 25-55 who have not had any morbidity that raises the need for antibiotics.

Together, these two segments cover a large portion of each of the two publics that choose to request or take antibiotics for upper respiratory infections. Each group will have six (6) to eight (8) participants, a well-researched optimum size for in-depth discussion (Stewart and Shamdasani, 1990).

A professional moderator from Balch Associates will guide the discussion of the focus groups, following a discussion guide comprised of key topics and trigger questions (Attachment 5). Observers from ORISE and NCIRD can call in from anywhere to observe the focus groups without being heard. The focus groups will be audio recorded and transcripts will be prepared from these recordings. A professional teleconference facility familiar with computer- assisted telephone (CAT) focus groups will provide digital fiber-optic telephone connections, operator services, and remote computer (“bridge”) connection for moderator to identify which participant is speaking at any moment, as well as audio recording, and transcription.

Analysis begins after the first focus group. The moderator and observers will review what was heard and learned toward the project goal and objectives. After the last focus group session a summary of findings is drafted and reviewed by the investigative team. A "topline report" is then fleshed out and modified, as needed, with verbatim quotes that are found in the transcripts. This "topline report" draft is reviewed by the team for needed changes and, most importantly, for suggestions on a new section called "Conclusions and Recommendations." After further review and revision, all sections are combined into a "Final Report."

A.3. Use of Improved Information Technology and Burden Reduction

Recruitment by email and telephone and data collection by focus groups by computer-assisted telephone conferencing will be used to reduce the burden on the public and maximize quality and efficiency of data collection, processing, and reporting. This is in compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII.

Recruitment will be done in two stages: (1) A brief (average 5 minute) set of six screener questions (See Attachment 1) is emailed in waves to members of a periodically updated nationwide proprietary database of individuals who have opted into it to participate in research. (2) As responses are received, the recruiters identify the pre-screened respondents (estimated at 384) whose responses to the pre-screener partly pre-qualifies them. They then telephone these individuals and interview them with a full screening/ invitation instrument, developed with specifications for two audience segments (Attachment 2). They continue emailing waves of pre-screeners and conducting screening interviews until all groups have been filled with qualified respondents.

Focus groups will be conducted via CAT methodology (Attachment 3) Participants participate from the comfort of their home, office, or other private place they choose where they have access to a phone. Everyone can hear everyone else clearly in real-time, which accelerates interaction (and production of clear recording and an accurate transcript). Interaction starts fast and is often more natural, open, and intense than in face-to-face groups, since participants use only first names and cannot be seen.

CAT focus groups are equally available to people from all over the U.S., including places (e.g., rural and unsafe neighborhoods) and kinds of people not otherwise available (e.g., disabled people and busy, protected executives). Compared to face-to-face focus groups, CAT focus groups are more representative and, faster to recruit. They have higher response rates, since they eliminate the costs, time, and inconvenience of travel and, therefore, require fewer screening interviews. Moreover, each focus group will take 90 minutes instead of the more common two hours.

A.4.Efforts to Identify Duplication and Use of Similar Information

The Get Smart: Know When Antibiotics campaign has worked with the CDC's Division Healthcare Quality and Promotion's (DHQP) Nadine Shehab and Daniel Budnitz, authors of the groundbreaking research related to antibiotics and adverse drug events, to ensure that efforts to educate the public about ADEs and antibiotics were not being duplicated. DHQP encouraged the Get Smart campaign to explore

messages with the public related to adverse drug events and inappropriate antibiotic use for URIs. The Get Smart campaign also conducted a literature review using the PubMed database to look for any educational programs specifically related to the dangers of inappropriate antibiotic use for URIs and adverse drug events. No programs were found. In addition, the Get Smart campaign has contacted several of their partners such as Food and Drug Administration, National Council on Patient Information and Education and others to discuss the topic and assure that efforts were not being duplicated.

A.5.Impact on Small Businesses or Other Small Entities

This section does not apply to general population telephone interviews. Participation in this study is only for individuals, not organizational entities, and is voluntary. No small business will be involved in this data collection.

A.6.Consequences of collecting the information less frequently

This will be a one-time data collection.

Failure to conduct formative research to develop messages about adverse drug events may leave the intended campaign well off target and less effective for educating the public about appropriate antibiotic use and, therefore, less effective in reducing serious and potentially deadly ADEs and needless health care costs. There are no legal obstacles to reduce the burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances. This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. The 60-day Federal Register Notice (FRN) for 0920-0798 was published in the Federal Register on May 14, 2008, Vol. 73, No. 94, pp. 27833-27834. The 30-day FRN was published on July 24, 2008, Vol. 73, No. 143, pp. 43241-43242. No public comments were received.

B. The people below were consulted for this study:

Individuals	Contact Information
Karen Werner, PhD, CHES	Oak Ridge Institute of Science and Education (ORISE) email:Karen.Werner@orise.orau.gov phone: 404-291-2236
Nichole Urban, MPH, CHES	Oak Ridge Institute of Science and Education (ORISE) Email: Nichole.Urban@orise.orau.gov Phone: 865-241-1321
George I. Balch, Ph.D.	Balch Associates E-mail: GIBalch@gmail.com phone: 708-383-5570

A.9. Explanation of any Payment or Gift to Respondents

Focus groups require more time than surveys. Consistent with commercial practice for highly select participants who are not executives or highly paid professionals, the recruitment agency will offer the participants for this study an honorarium of $50 for their time. The recruitment agency will send a check directly to the participant or to a charity of the participants' choice.

Message exploration is a marketing technique used among commercial researchers and it is standard practice to provide incentives to recruit participants for the studies. Incentives have been found to increase response rates, which improves the quality of data. Most research concludes that monetary incentives paid directly to the participant are the most effective (Singer et al, 1999).

A.10. Assurance of Confidentiality Provided to the Respondents

No record is made that links identifying information with what is said in the focus group sessions. Participants are assured of their privacy. All participants are provided a Participant Information sheet (See Attachment 4), which states: "We will keep the information you give us private and secure. Your name will not be used in any report. No statement you make will be linked to you by name. Only members of the research staff will be allowed to look at the records. When we present this study or publish its results, your name or other facts that point to you will not show or be used."

Health Marketing, 0920-0798 received an exemption from IRB. Dr. Kathleen Y. McDuffie stated "The health marketing project's sole purpose is to provide the CDC with high-quality timely information that will provide guidance to reaching and listening to the people, families and communities that the agency serves. The information gathered in the process will be utilized to tailor messages, use appropriate distribution and feedback channels, partnerships and communication modes as a response to urgent events or realities. This project is deemed as public health practice and non research and therefore, does not require IRB review."

Privacy Impact Assessment Information

A. The consultant will not send CDC any personal identifiers (full name, address, phone numbers, social security numbers, etc.) for participants other than their first names. Participants do not use their last names or any other personal identifiers during focus group sessions. No records are made that link personal identifiers to the results.

B. Notes, recordings, and transcripts will be kept in a locked facility until shipped to ORISE and CDC, where the documents will be kept in locked filing cabinets except if in use. Any notes taken will be held close during data collection. Only personnel conducting the study will have access to notes, recordings, or transcripts. The information will be kept for 3 years after the study. After the 3 years the documents and audio tapes will be burned or shredded.

C. Participants will not sign a consent form but will be informed of their rights as a study participant. Prior to participating in the study, each prospective respondent will receive an information sheet providing such information as sponsorship of the study, their rights as participants, risks and benefits in participating, and contacts for more information. (See Attachment 4)The moderator will address any questions the participants have about the study before the focus group begins.

D. The Participant information Sheet also informs the participants that the study is voluntary and they are not required to answer the questions. The document also informs the participants of the cash incentive, and that the participants will be able to leave at any time without losing their cash incentive or other penalty. The respondents are also informed that their responses will be treated in a secure manner and reported in the aggregate manner.

A.11. Justification for Sensitive Questions

The recruitment agency will ask the participants' race and ethnicity to assure, to the extent feasible, representation of the largest minority racial and ethnic groups of the U.S. population for the study. No other sensitive information will be collected. However, respondents will be informed that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.

A.12. Estimates of Annual Burden Hours and Costs

Table A. 12-A & B. Estimated Annualized Burden Hours

Form Name	Type of Respondents	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Pre-screener	General Public	1,500	1	5/60	125	$19.56	$2,445.
Screener	General Public	384	1	10/60	64	$19.56	$1,251.84
Focus groups	General Public	48	1	1.5	72	$19.56	$1408.32
	Total				261		$5105.16

* According to the U.S. Department of Labor (DOL), Bureau of Labor Statistics, Occupational Employment Statistics, May 2007 National Occupational Employment and Wage Estimates the mean hourly wage for all occupations was $19.56.

A.13. Estimates of other total annual cost burden to respondents or record keepers.

Respondents will not need capital equipment, on-going recordkeeping operations, or services to complete the information collection. There are no costs to the respondents except their time.

A.14. Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Personnel	Darcia Johnson is a program officer for the Get Smart campaign. She is a full-time employee and is a contractor with the P3S Corporation contracting company. Five percent of Darcia's time is dedicated to this project.	$3000.00
Personnel	Lauri Hicks, DO Medical Officer for the Get Smart Campaign. 1% of Dr. Hicks time is dedicated to this project.	$1,500.00
Inter-agency Agreement	Inter-agency agreement with ORISE	$245,000.00
	TOTAL	$248,000.00

A.15. Explanation in Program Changes or Adjustments

No change. This is a new data collection.

A.16. Plans for tabulation and publication and project time schedule

Tasks Accomplished	Anticipated Dates
All Focus Group Participants Recruited	3 weeks following approval
All Focus Group Sessions Conducted	7 weeks following approval
All Focus Groups Sessions Transcribed	8 weeks following approval
Top-line Summary Drafted	9 weeks following approval
ORISE/CDC Initial Feedback Provided	10 weeks following approval
Revisions made and "Findings, Recommendations, and	12 weeks following approval

Conclusions" enhanced by thematic analysis of transcripts and recordings	
ORISE/CDC Second Review and Feedback Provided	13 weeks following approval
Full Report Drafted	14 weeks following approval
ORISE/CDC Third Review and Feedback Provided	15 weeks following approval
Final Content Revisions Made	16 weeks following approval
Copy-edited and submitted to Desk-top Publishing	17 weeks following approval
Final Report Submitted	18 weeks following approval

A.17. Reason Display of OMB Expiration Date is Inappropriate.

Not Applicable

A.18. Exceptions To Certification for Paperwork Reduction Act Submissions.

There are no exceptions to the certification.

Attachments

Attachment 1	Pre-Screener
Attachment 2	Recruitments and Specification Screener
Attachment 3	Computer Assisted Telephone “CAT“ Blurb
Attachment 4	Participant Sheet
Attachment 5	Discussion Guides

References

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